UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,504	03/05/2007	Atsuko Fukui	MATOB1.001APC	4157

20995 7590 09/30/2011

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
09/30/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
efiling@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/571,504	FUKUI, ATSUKO	
	Examiner	Art Unit	
	NISSA WESTERBERG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *2-12* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *2-12* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments, filed September 12, 2001, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 2 - 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villagran et al. (US 6,180,159).

Villagran et al. discloses flavored beverage product that preferably comprises about 0.2 – 5% fat/oil; about 0.05 – 2.0% thickener; an effective amount of sweetener such as about 0 – 10% and water (e.g., col 14, ln 44 – 65; claim 12). These beverages are creamy, rich and preferably foamy with a clean, improved mouthfeel that are thickened while not being slimy or stringy (col 13, ln 2 - 7). The fat/oil can be soybean oil, corn oil, cottonseed oil, palm oil, coconut oil, canola oil, fish oil, lard or tallow (col 5, ln 50 – 62), which read on the vegetable/animal fat/oil recited in instant claim 10. The thickener can be locust bean gum, guar gum, gellan gum, xanthan gum and carrageenan, among others (col 10, ln 52 – 7; claim 7). The sweetener can be sugar or sugar alcohols such as sorbitol (col 11, ln 60 – 65). The beverage products also contain buffers that maintain the pH of the finished beverage between 6.2 and 7.0 for optimal stability and flavor (col 10, ln 43 – 51). Dried particles in the micron size range are prepared to provide a more dense product with better consumer dissolvability (col 14, ln 25 – 40) and will hydrate in the final product to produce larger sized granules. Emulsifiers can also be included in the beverage, in amounts preferably ranging from about 0.004 - about 0.2% (col 14, ln 56 - 58), and can be long chain fatty acids but also esters such propylene glycol esters, propylene glycol monoesters, polyglycerol esters, sucrose monoesters and sorbitan esters, which read on the hydrofuge inhibitor component of claim 3 (col 7, ln 42 - col 8, ln 4).

Villagran et al. does not explicitly describe the production of a beverage that contains thickener, fat/oil, emulsifier (the hydrofuge inhibitor of the instant claims), and a sugar alcohol sugar such as sorbitol.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to prepare such a drink as taught by Villagran. The selection of ingredients for the beverage will be determined by the type of beverage product and the desired properties (e.g., sweetness) of the final beverage. The amounts of these ingredients either are contained within or overlap the ranges of amounts of these ingredients and overlapping ranges are prima facie obvious (see MPEP 2144.05).

In regards to claims 4 and 5, the prior art is silent as jelly strength and size of the granules that form when the jelly drink is prepared. “As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” **MPEP 2113** Therefore, the burden is shifted to applicant to demonstrate that the products of Villagran do not meet these claim limitations as they will have jelly strength and granule size, but the particular value of these parameters cannot be determined by the Patent Office.

The administration with a particular drug (e.g., antibiotics) or drug form (e.g., uncoated tablets) is a recitation of the intended use of the composition. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the

intended use, then it meets the claim. The beverage products of Villagran can be used to take medications such as those recited by the instant claims and thus the intended use recitation is meet.

The composition must also be "adapted to be mixed by an end user with said medicine and/or dietary supplement". This limitation also relates to the intended use and a review of specification did not reveal any particular structure or ingredients not found in Villagran that would render the beverages of Villagran not adapted to be mixed by an end user with a medicine or dietary supplement.

5. Claims 4 - 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukui et al. (US 6,277,395) in view of Nakagami et al. (WO 00/54811; all citations from IS 2005/0152975, a continuation of the PCT application) and Gowan, Jr. et al. (US 5,374,659). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 12, 2011 and those set forth below.

Fukui et al. discloses swallowing assistive drinks made using water and an adhesive paste that provides viscosity to the water upon mixing (col 3, ln 24 – 32). The compositions preferably have a jelly strength at 20°C of 10-100 g/cm^2 (col 3, ln 40 - 46). Patients can have difficulty swallowing, can choke or not take the full dose of medicine when it is administered in forms such as powders (col 1, ln 17 – 21). The swallowing assistive drink improves the swallowing of various medicines while remaining convenient for use because of the use of ordinary water to prepare (col 1, ln 47 – 53). The granules are readily swallowed and do not stick in the mouth because they are

enwrapped by the drink (col 4, ln 35 – 43). Agar, carrageenan, gellan gum, furcellan, gelatin, locust bean gum, guar gum, xanthan gum, arginic acid, psyllium seed gum or tamarind gum (col 3, ln 32 – 39). 8-10 wt % sugars including the sugar alcohols mannitol and erythritol can be included in the drink (col 4, ln 1). Various jellied drinks are prepared in the examples and they generally contain about 8.8 wt % sugar alcohol (mannitol or erythritol) and between 0.32 % and 2 wt % total of gelatinizing agents (the formulations use more than one such agent).

Fukui does not disclose the presence of at least one of a vegetable fat, vegetable oil, animal fat or animal oil drink that does not contain the medicament.

Nakagami et al. discloses granular pharmaceutical compositions that mask the disagreeable taste of the drug and provides a favorable sensation upon oral administration (¶ [0001]). The addition of a sugar alcohol to the drug and wax substance provides a formulation with excellent ability to mask the taste and provide a favorable sensation (¶ [0007]). The waxes that can be used are hydrogenated oils such as the vegetable oils soybean and rape seed; fats and oils of vegetable or animal origin; fatty acids and derivatives such as fatty acid glycerin esters and fatty acid sucrose esters and mixtures of two or more of these substances (¶ [0054]). These waxes read on the bitterness masking component of the instant claims. The wax is melted and the drug is dissolved or dispersed therein (¶ [0057]).

Gowan, Jr. et al. discloses an aqueous pharmaceutical suspension of a water insoluble pharmaceutical active agent; xanthan gum in an amount to stabilize the suspension; starch and polyoxyethylene sorbitan monooleate; and an effective amount

of a taste masking composition and water (col 2, ln 15- 25). Among the active agents that can be used in the formulation is the macrolide antibiotic erythromycin estolate (col 3, ln 45).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate a fat or oil in combination with sugar alcohol to mask the taste of the bitter medicament. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Gowan, Jr. et al. discloses that the bitter tasting medicine need not be directly coated with the taste masking, as in Nakagami, but rather can be contained in the medium surrounding the drug. The swallowing assistive drink of Fukui acts as the carrier with the user providing the drug to be masked to form a taste masked suspension like that taught in Gowan, Jr. et al.

In regards to claim 5, the prior art is silent as to the size of the granules that form when the jelly drink is prepared. “As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” **MPEP 2113** Therefore, the burden is shifted to applicant to demonstrate that the products of Fukui and Villagran do not meet these claim limitations as they will granule size, but the particular value of these parameters cannot be determined by the Patent Office.

Applicants traverse this rejection on the grounds that the proposed modification of Fukui would render it unsuitable Fukui is directed towards a composition in which

mixing of the drink and the medication in the patients mouth or prior to being poured in the mouth, while Nakagami melts wax and then disperses the drug uniformly in the wax. Fukui can be readily prepared by the end user, but the user could not readily carry out the wax bitterness masking of Nakagami. The process of Nakagami is expensive and time consuming. Gowan only discloses sugar alcohols rapidly dissolve in the mouth while the wax granules of Nakagami have only a very low solubility in the mouth and Gowan does not disclose other taste masking components such as wax particles.

These arguments are unpersuasive. Nakagami teaches a taste masking combination of wax and sugar alcohol that provides better taste masking than sugar alcohols alone. The operability of Fukui is not destroyed when waxes in small quantities would be added to the liquid assistive drink to impart additional taste masking to the formulation. The teachings of Fukui and Gowan teach that the taste masking ingredients need not be coated around the drug granule in order to be efficacious in masking the taste of bitter ingredients also present in the composition and Fukui teaches that the drink enwraps the granules, so the wax present in the drink will also ‘enwrap’ the granules, although not on the same physical scale as the drug granules coated with wax and sugar alcohol in Nakagami. Applicants present no persuasive arguments that the person of ordinary skill in the art would not have a reasonable expectation of success in concluding that the addition of wax would not impart additional taste masking benefits to a liquid formulation.

6. Claims 2 and 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fukui in view of Nakagami and Gowan, Jr. et al. as applied to claims 4 - 12 above, and further in view of Villagran et al. (US 6,180,159).

Fukui in view of Nakagami and Gowan, Jr. et al. are discussed above.

Nakagami et al. does not explicitly described the use of a combination of vegetable or animal fat or oil with one of the hydrofuge inhibition components in the Markush group of claim 3 such as fatty acid glycerin esters and fatty acid sucrose esters or disclose the pH of the final composition.

Villagran is as discussed above.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate emulsifiers (the hydrofuge inhibitor components of the instant claims) and to prepare a beverage having a pH of 6.2 - 7.0 for optimal stability. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because emulsifiers add in keeping the fat and water ingredients dispersed in solution and the pH will influence the stability and shelf life of the prepared.

7. Claims 2 - 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukui (US 6,277,395) in view of Villagran (US 6,180,159).

Fukui is discussed above.

Fukui does not disclose the presence of animal/vegetable fat or oil in the composition, the pH of the beverage or the presence of a hydrofuge inhibitor listed in claim 2.

Villagran is discussed above.

It would have been obvious to add a fat/oil and an emulsifier (the hydrofuge inhibitor compound of the instant claims) as Villagran discloses that such ingredients can be added to beverages. The fat/oil will alter the mouth feel of the composition and the emulsifiers will aid in keeping the oil/fat ingredients dispersed with the water soluble ingredients and water also present in the beverage. The selection of ingredients for the beverage will be determined by the type of beverage product and the desired properties (e.g., sweetness) of the final beverage. The amounts of these ingredients either are contained within or overlap the ranges of amounts of these ingredients and overlapping ranges are prima facie obvious (see MPEP 2144.05). Villagran also discloses that a pH of slightly acidic (6.2 - 7) is a desirable pH range for these beverage products.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 2 - 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 12 of copending Application No. 12/682747. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 12, 2011 and those set forth below.

Applicants traverse this rejection on the grounds that as all the rejections have been overcome and the instant application is earlier filed, this rejection should be withdrawn as this is the only rejection remaining.

As detailed above, the claims of the instant application are not in condition for allowance so the provisional double patenting rejection is not the only remaining rejection and will be maintained for the reasons of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NISSA WESTERBERG whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nissa M Westerberg/
Primary Examiner, Art Unit 1618